



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,964	06/14/2005	Doug Sweet	09138.0069	5627
63432 7590 10/01/2008 DAKO/FINNEGAN, HENDERSON, LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413				
EXAMINER HENKEL, DANIELLE B				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
10/01/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,964

Applicant(s)

SWEET ET AL.

Examiner

DANIELLE HENKEL

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-85/86)
- Paper No(s)/Mail Date 10/12/08 and 6/14/05
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Inventor's Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Summary

1. This is the initial Office action on the 10/538964 application filed on June 14, 2005.
2. Claims 1-34 are pending and have been fully considered.

Election/Restrictions

3. Applicant's election with traverse of claims 1-5, 8-20, and 30-34 in the reply filed on August 21, 2008 is acknowledged. The traversal is on the grounds that the groups of inventions do have unity of invention. This is found persuasive and claims 6-7, and 21-29 are rejoined.

Information Disclosure Statement

4. The information disclosure statement filed 10/12/06 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language, specifically FR 2239167, DE 69417908, and ES 2160486.

Specification

5. The use of the trademark INFOGLYPH™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 17 recites the limitation "said tissue sample" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim. The examiner assumes this limitation to be referring to the said sample.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by RHETT (US 5839091).

a. With respect to claim 1, RHETT teaches an automatic tissue specimen staining apparatus and method for staining tissue specimens (samples) on glass slides held in separate slide racks (separate staining sections) (Column 3, lines 28-31). The apparatus also includes reagent vials (containers) stored in reagent racks (reagent section) (Column 3, lines 49-50). A robotic delivery system controlled by a personal computer delivers reagents from the vials to the slides (affects reagent and sample) (Column 3, lines 35-40). RHETT teaches the apparatus can also include a CCD camera (optical sensor) to image the stained slides (one element) (Column 14, lines 5-8).

b. With respect to claim 9, RHETT teaches a reagent container, slide samples, robotic element and control elements (see rejection of claim 1). RHETT also teaches the sample slides are in four racks (at least first and second slide sections) (Column 3, lines 29-30) but does not teach the reagent section between the slide sections. It would have been obvious to one having ordinary skill in the art at the time of the invention to place the reagent section between the slide sections, since it has been held that rearranging parts of an invention involves only routine skill in the art (*In re Japikse*, 86, USPQ 70; MPEP 2144.04 (VI-C)).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 2-8, and 10-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over RHETT (US 5839091), and further in view of GANZ (WO 02/064812).

a. With respect to claim 2, RHETT does not explicitly disclose the optical sensor adapted to locate reference features to calibrate the robotic element.

However, GANZ teaches an automated dispensing device to place reagents on slides in which a camera (optical sensor) images each slide and inspects

(adapted to locate) the positioning and alignment of the slide (Page 5, Paragraph

5). Software in the control element analyzes this position data and uses it to adjust (self calibration) the positions of the slide and dispense head (robotic

element) (Page 6, Paragraph 1). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the automatic tissue stainer of RHETT to include the camera adapted to calibrate the robotic element of GANZ because it ensures accurate placement of the reagent on the slide preventing inaccurate results (Page 6, paragraph 1). RHETT and GANZ are analogous art because they are from the same field of endeavor of automated biological processing for analysis of slide samples.

b. With respect to claim 3, RHETT teaches using a CCD camera (optical sensor) to capture (record) images of the stained slides (finalized sample after staining) (Column 14, lines 5-8).

c. With respect to claim 4, RHETT teaches recording images of the slides after staining, but does not explicitly disclose the optical sensor imaging a barcode. However, GANZ teaches the camera reads a bar code located on the slide (Page 5, Paragraph 5) because it allows for verification of slide identification information and enables the computer (control element) to track each slide (Page 3, paragraph 1; Page 5, paragraph 1).

d. With respect to claim 5, RHETT teaches recording images of the slides after staining, but does not explicitly disclose the optical sensor configured to identify an identification feature of the sample. However, GANZ teaches the camera reads a bar code (identification feature) located on the slide (Page 5, Paragraph 5) because it enables the computer (control element) to track each slide (Page 3, paragraph 1).

- e. With respect to claim 6, RHETT teaches the claimed invention (see rejection of claim 1), but does not explicitly disclose recording image data, robotic calibration points, and feeding the data to a control element. However, GANZ teaches a camera that images the slides and software that analyzes the identification, positioning (robotic calibration reference points) and alignment information (relevant image data) provided by the camera and stores it (records) (Page 5, paragraph 5—Page 6, paragraph 1). GANZ teaches the camera sends the image information to software on a computer (control element) which uses the information to adjust the positions of the dispense head (responsive robotic element) (Page 6, paragraph 2) because it ensures accurate placement of the reagent on the slide preventing inaccurate results (Page 6, paragraph 1).
- f. With respect to claim 7, RHETT teaches the claimed invention (see rejection of claim 1), but does not explicitly disclose the optical sensor responsive to the robotic element. However, GANZ teaches the camera (optical sensor) images the slide after the linear actuator (robotic element) moves the slide under the dispense head, therefore the optical sensor must respond to placement by the robotic element because this allows the camera to acquire position and alignment information of the slide (Page 6, paragraph 2). GANZ also teaches the camera images the slides and software analyzes the identification, positioning (robotic calibration reference points) and alignment information (relevant image data) provided by the camera and stores it (records) (Page 5, paragraph 5—Page 6, paragraph 1). GANZ teaches the camera sends the image information to

software on a computer (control element) which uses the information to adjust the positions of the dispense head (responsive robotic element) (Page 6, paragraph 2) because it ensures accurate placement of the reagent on the slide preventing inaccurate results (Page 6, paragraph 1).

g. With respect to claim 8, RHETT teaches the claimed invention (see rejection of claim 1) but does not explicitly disclose the optical sensor adapted to locate reference features for self calibration. However, GANZ teaches an automated dispensing device to place reagents on slides in which a camera (optical sensor) images each slide and inspects (adapted to locate) the positioning and alignment of the slide (Page 5, Paragraph 5). Software in the control element analyzes this position data and uses it to adjust (self calibration) the positions of the slide and dispense head (robotic element) (Page 6, Paragraph 1) because it ensures accurate placement of the reagent on the slide preventing inaccurate results (Page 6, paragraph 1).

h. With respect to claim 10, RHETT teaches the claimed invention (see rejection of claim 1) except for one element comprising an optical identification element having reiterated information. However, GANZ teaches the slides having identification information comprising unique 2D bar codes which are reiterated lines because it allows for identification and tracking of the slides by the control element (Page 5, paragraph 4).

i. With respect to claims 11-16, the slide identification information (optical identification) in the form of a barcodes as taught by GANZ which are by

definition multiple iterations of lines in patterns which may repeat (redundant). It would have been obvious to one having ordinary skill in the art to use two dimensional high resolution symbology or data matrix codes in the optical identification art and selection of any of these known equivalents to use as slide identification in place of a barcode would be within the level of ordinary skill in the art (MPEP 2144.06).

j. With respect to claim 17, RHETT teaches the claimed invention (see rejection of claim 1) except for a computer image biological analysis element. However GANZ teaches the control computer has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample (Page 10, Paragraph 2).

k. With respect to claim 21, the above combination of RHETT and GANZ in the rejection of claim 6 teaches the claimed invention except for biologically analyzing image data of a sample with a computer. However, GANZ teaches the control computer has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample (Page 10, Paragraph 2).

l. With respect to claim 25, the above combination of RHETT and GANZ in the rejection of claim 7 teaches the claimed invention except for biologically analyzing image data of a sample with a computer. However, GANZ teaches the control computer has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample (Page 10, Paragraph 2).

- m. With respect to claim 30, the above combination of RHETT and GANZ in the rejection of claim 17 teaches the claimed invention except for a multifunction optical sensor. However the camera (optical sensor) of GANZ is disclosed to read barcodes and inspect the positioning and alignment of a slide (multiple functions) because having one optical sensor to complete multiple functions would save on space and manufacturing costs.
- n. With respect to claims 18, 22, 27, and 32, RHETT teaches using a camera to capture images of the slides (Column 14, lines 6-8).
- o. With respect to claims 19, 23, 28, and 33, RHETT specifically teaches using a CCD camera (Column 14, lines 6-8).
- p. With respect to claims 20, 24, 26, and 31, RHETT teaches staining tissue specimens (biological samples) placed on glass slides (Column 3, lines 27-28).

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is (571)270-5505. The examiner can normally be reached on Mon-Thur: 7:30am-5pm, Alternate Fridays: 7:30am-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DBH

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797